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FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
DICKINSON, PAUL W	
ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,603	FRAYSSINET ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *14-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/28/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 4/26/2010 is acknowledged. The traversal is on the ground(s) that the biocompatible composite material of EP 0361797 (EP '797) is not degradable. The material of EP '797 is very stable and by contrast Applicant's material is very unstable. As the biocompatible composite material of EP '797 is very stable, it is not degradable, and therefore does not anticipate the claimed invention nor break unity of the claimed invention.

This is not found persuasive because the material of EP '797 meets all the structural limitations of Applicant's material. EP '797 discloses a material that consists of a hydroxyapatite matrix (a degradable biocompatible phosphocalcium matrix), the hydroxyapatite matrix containing magnetic particles (see abstract; page 2, line 42 to page 3, line 21). A composition cannot be separated from its properties. Accordingly, as the material of EP '797 is structurally identical to the presently claimed material, then it must be degradable. Furthermore, page 2, line 27 of EP '797, cited in the reply, states that "the present invention seeks to provide ceramics body to be embedded in living tissues, which is innocuous and stable for a long period when embedded in living tissues". Being stable for a long period implies that, at some point after implantation, the material does degrade. Thus, the material of EP '797 must be degradable because (1) it meets all of the structural limitations of instant claim 1 and (2) the reference itself implies that it degrades.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claims 4-5 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The biocompatible degradable composite material of claim 1 is closed to further unrecited components ("characterized in that it consists of"). Claim 4 adds further unrecited components ("...further comprises calcium sulfate"). Claim 5 adds further unrecited components ("characterized in that it further consists of..."). Accordingly, claims 4-5 fail to further limit claim 1.

Improper Subject Matter

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 provides for a use of the material according to claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending the claim to encompass.

A claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Furthermore, a claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

A single claim which recites both a product and method steps of using that product is indefinite under 35 USC 112, second paragraph. See Ex parte Lyell, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990). Such claims should also be rejected under 35 USC 101 on the theory that the claim is directed to neither a "process" nor a "machine", but rather embraces or overlaps two different statutory categories of invention set forth under that statute, which is drafted so as to set forth the statutory classes of invention in the alternative only. Id. At 1551.

Instant claim 12 recites both a product (the material according to claim 1) and a process (forming a mineral matrix)). Claim 12 is thus rejected as follows on the theory that the claim is directed to neither a "process" nor a "product" exclusively:

1) Claim 12 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

2) Claim 12 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of "a few days" and "a few weeks" is unclear. The term "a few" is a relative term. This term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the term. Does "a few" mean 3, 10, 100, etc?

In claim 2, is the "calcium phosphate" the "phosphocalcium matrix" of claim 1? A "phosphocalcium matrix" would reasonably be a matrix that requires phosphocalcium, but "phosphocalcium" and "calcium phosphate" are not necessarily equal terms. For clarity, the "phosphocalcium matrix" in claim 1 should be rewritten as "calcium phosphate matrix" or alternatively "calcium phosphate" in claim 2 should be rewritten "phosphocalcium". Such agreement between these terms would be clear.

In claim 3, the term "rapidly" is a relative term which renders the claim indefinite. The term "rapidly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

In claim 4, it is unclear if "further comprising calcium sulfate" is intended to add a calcium sulfate to the material of instant claim 1. Claim 1 is closed to addition of such further unlimited components ("a biocompatible degradable composite material characterized in that it consists of..."), so it is unclear how it could have calcium sulfate additionally added. However, "further comprising calcium sulfate" could be interpreted to mean that the "phosphocalcium and/or calcium sulfate matrix" of claim 1 is a calcium sulfate matrix. For these reasons it is unclear what role the further calcium sulfate of claim 4 has in claim 1.

In claim 7, the phrase "contain a metal, notable iron, preferably as..." renders the claim indefinite. The terms "notably" and "preferably" render the claim indefinite because it is unclear whether the limitations following the terms are part of the claimed invention. Similarly, "such as" in claim 13 is indefinite because it is unclear whether the limitation following this phrase are part of the claimed invention. See MPEP § 2173.05(d).

In claim 9, "characterized in that said magnetic particles are vectors either of a molecule used in chemotherapy or an isotope" is indefinite. Firstly, the language is open to multiple interpretations: (1) the magnetic particle may be a vector of a molecule used in chemotherapy or alternatively the magnetic particle may be an isotope, (2) the magnetic particle may be a vector of a molecule used

in chemotherapy or a vector of an isotope. Secondly, how can a magnetic particle be a molecule used in chemotherapy? A magnetic particle may comprise or consist of a molecule used in chemotherapy, but a magnetic particle cannot be molecule used in chemotherapy.

In claim 13, it is unclear if the "particles coated with a calcium phosphate layer containing a fluorescent element" correspond to the magnetic particles of claim 1. If so, claim 13 should recite "magnetic particles" to give this term clear antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 12-13 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by US 20030082232 ('232). '232 discloses a biocompatible degradable composite material (see abstract), characterized in that it consists of

a degradable biocompatible phosphocalcium and/or calcium sulfate matrix (paragraph 25), said matrix containing magnetic particles (paragraph 71), said material being found as a slurry during its introduction into the organism, as a solid subsequently (paragraphs 91-92) and said matrix being resorbed within a period of a few days to a few weeks (paragraph 28)

The calcium phosphate may be amorphous calcium phosphate (paragraph 25). The material may additional comprise collagen (see paragraph 43) and polylactic and polyglycolic acids (paragraph 67). The matrix has biocompatibility and degradation characteristics compatible with applications of the material for treating bone tumors (paragraph 71). The matrix comprises particles coated with a calcium phosphate layer containing a fluorescent element (see paragraph 85).

Claims 1-4, 6-9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0361797 (EP '797). EP '797 discloses a degradable biocompatible composite material that consists of a hydroxyapatite matrix (a degradable biocompatible phosphocalcium matrix), the hydroxyapatite matrix containing magnetic particles (see abstract; page 2, line 42 to page 3, line 21). The magnetic particle may comprise ferrite (see paragraph 33). The material may be administered by a variety of forms, including intravenous injection, subcutaneous injection, and oral administration (see paragraph 34).

The phrase "said material being found as a slurry during its introduction into the organism, as a solid subsequently and said matrix being resorbed within a period of a few days to a few weeks" in claim 1 is an intended use. The

recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the biocompatible degradable composite of EP '797 meets all the structural limitations of the instant claims and is fully capable of being administered as a slurry during its introduction into an organism, as a solid subsequently and said matrix being resorbed with a period of a few days to a few weeks.

EP '797 does not appreciate that its degradable biocompatible composite material "has biocompatibility and degradation characteristics with applications of the material for treating bone tumors" (instant claim 6). However, a composition cannot be separated from its properties, and as the material of EP '797 is structurally indistinguishable from the material of claim 6, it must inherently have biocompatibility and degradation characteristics with applications of the material for treating bone tumors.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 20030082232 ('232) in view of Widder (European Journal of Cancer and Clinical Oncology, 1983). The relevant portions of '232 are given above. '232 fails to teach iron particles. '232 further fails to teach magnetic particles that are vectors either of a molecule used in chemotherapy or an isotope. '232 further fails to teach the magnetic particle sizes of 0.001 to 0.1 microns nor 0.1 to 10 microns. However, '232 incorporates by reference Widder as examples of magnetic particles that may be incorporated into its composition (paragraph 71).

Widder discloses magnetically response albumin microspheres to treat tumors (abstract). The microspheres comprise iron in the form of magnetite (Examples). The exemplified microspheres have an average diameter of about 1 micron (abstract; Examples).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to incorporate the microspheres of Widder into the

composition of '232, to treat tumors, as this is one embodiment of the invention taught by '232. The microspheres have an average diameter of about 1 microns which anticipates 0.1 to 10 microns (instant claim 11). This is an average diameter, however, and due to particle size distribution inherent in microparticle formulations, it is reasonable that at least some portion of the microparticles have diameters between 0.001 to 0.1 microns (instant claim 10).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

July 12, 2010